UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,065	03/06/2001	Donald H. Bouyer	026.00121	4126

7590 05/01/2003

Susan J. Braman
Braman & Rogalskyj, LLP
P.O. Box 352
Canandaigua, NY 14424-0352

EXAMINER	
GRASER, JENNIFER E	

ART UNIT	PAPER NUMBER
1645	10

DATE MAILED: 05/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/800,065	Bouyer et al.
Examiner	**Art Unit**
Jennifer Graser	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Amendt. A/Election, 4/3/03*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above, claim(s) *12, 17-20, and 22-42* is/are withdrawn from consideratio

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-11, 13-16, and 21* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I (claims 1-11, 13-16 and 21) in Paper No. 9A is acknowledged. The traversal is on the ground(s) that claim 25, which was newly amended after the Restriction Requirement was made in order to make it dependent on claim 1, is now a linking claim and, therefore, Groups VI and VII, which are drawn to proteins and antibodies should be examined along with the DNA of Group I. This has been fully and carefully considered, but is not found persuasive because claim 25 is not a true linking claim as it is merely stating that the DNA of claim 1 encodes the protein that is being claimed in claim 25. Claims 1 and 25 are both product claims and therefore claim 25 cannot be a true linking claim. More specifically, claim 25 does not meet any of the definitions of a linking claim set forth in MPEP 809.03, i.e., it is not a species of claim 1, nor is it a process of making, or a means for practicing a process linking proper apparatus and process claims. Applicants are not entitled to the examination of multiple patentably distinct and independent inventions merely by throwing in a dependency. The protein of claim 25 is still patentably distinct and independent from the DNA of claim 1 and Group I. DNA, antibodies and proteins are biologically, chemically and structurally different products which are patentably distinct and independent inventions. The novelty of the protein does not reside solely in the DNA sequence which encodes it and claim 25 does not recite that the DNA is necessary to make the protein. In fact, recombinant methods of making the protein are Grouped with the DNA in elected Group I. It is possible for a DNA to be

novel, while its corresponding protein is already known in the art and vice versa. Inventions I, VI, VII and VIII are drawn to products which are biologically, chemically, and structurally different and, therefore, represent patentably distinct and independent inventions. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, and because the literature search for the Groups would not be coextensive, restriction for examination purposes as indicated is proper.

Claims 12, 17-20 and 22-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic claim.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-11, 13-16 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 6-10, and 13-16 are vague and indefinite because the mere recitation of a name, R.felis outer membrane protein, to describe the invention is not sufficient to satisfy the Statute's requirement of adequately describing and setting forth the inventive concept. The claims does not recite any structure for the protein or the nucleic acid molecule, nor does it even mention the

size or molecular weight of the outer membrane protein. Claims drawn to nucleic acid require a specific structure be recited in the claim. The claim should provide any structural properties, such as the nucleic acid sequence of the nucleic acid being claimed or the amino acid which the protein encodes, which would allow for one to identify the protein without ambiguity. The mere recitation of a vague name or type of protein does not adequately define the claimed nucleic acid. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed. The sequence of the nucleic acid molecule being claimed must be recited.

Claim 8 is vague and indefinite because it is unclear what is encompassed by "at least a portion of". This terminology reads on as little as one nucleotide. The claim should specify "full-length" complements or should be limited to specific functional portions which are defined by the specification, i.e., nucleotides x-y of SEQ I D NO:1 (if the specification so permits).

The wording of claim 21 is vague and confusing. It is unclear if this is a fusion or hybrid sequence? Are the first and second nucleic acid sequences linked or fused? Additionally, what changes are allowed in the 90% identical protein. What would be the structure of the DNA encoding this variant? Would it have function?

Claims 9 and 13 should be amended to recite "host cell" because the use of the term "cell" makes it sound as if it is a product of nature.

Claim Rejections - 35 USC § 112-Scope of Enablement

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-3, 6-11, 13-16 and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "an isolated nucleic acid molecule comprising SEQ ID NO:1" and "an isolated nucleic acid molecule which encodes the amino acid as shown in SEQ ID NO:2", expression vectors and host cells comprising said nucleic acid molecules and methods of recombinantly producing a protein using said nucleic acid, does not reasonably provide enablement for "an isolated nucleic acid molecule encoding *any* Rickettsia felis outer membrane protein", host cells, expression vectors and recombinant methods using this nucleic acid are also not enabled. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The instant claims are broadly drawn to the isolated nucleic acid molecules which encode ***any*** *Rickettsia felis* outer membrane protein. *Rickettsia felis* comprises many, very different outer membrane proteins on its outer membrane. The specification has only identified the nucleic acid encoding a single outer membrane protein which is set forth in SEQ ID NO:1. This single nucleic acid molecule does not enable all other outer membrane proteins found on the surface of *Rickettsia felis*. It would take undue experimentation on the part of the skilled artisan

to discover any other isolated nucleic acid sequences which encode a *Rickettsia felis* outer membrane protein. Adequate written description and enablement requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid itself is required. While Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. Therefore only 'an isolated nucleic acid molecule comprising SEQ ID NO:1' and 'an isolated nucleic acid molecule which encodes the amino acid as shown in SEQ ID NO:2', but not the full breadth of the claims meets the enablement description provisions of 35 USC 112, first paragraph.

With respect to claims 8 and 21, the breadth of the instant claims contain nucleotide sequences other than what is specified in the sequence disclosure. The specification states that substitutions, additions, or deletions may be made to the defined sequences; however, the specification provides no guidance as to what nucleotides may be changed without causing a detrimental effect to the protein to be produced. Further, it is unpredictable as to which nucleotides could be removed and which could be added. While it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where amino acid substitutions can be made with a reasonable expectation of success are limited. Other positions are critical to the protein's structure/function relationship, e.g., such as various positions or regions directly involved in binding, catalysis in providing the correct three-

dimensional spacial orientation of binding and catalytic sites. These regions can tolerate only very little or no substitutions. To start with the DNA sequence first, this requires even more work on the part of the skilled artisan. Applicants have provide no guidance to enable one of ordinary skill in the art how to determine, without undue experimentation, the effects of different nucleotide substitutions and the nature and extent of the changes that can be made. Given the lack of guidance contained in the specification and the unpredictability for determining acceptable nucleotide substitutions, one of skill in the art could not make or use the broadly claimed invention without undue experimentation.

Claim Rejections - 35 USC § 112-Written Description

6. Claims 1-3, 6-11, 13-16 and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description in this case only sets forth SEQ ID NO:1 and equivalent degenerative codon sequences thereof, i.e., isolated nucleic acid encoding the amino acid sequence as shown in SEQ ID NO:2, and therefore the written description is not commensurate in scope with the claims which only specify "an isolated nucleic acid encoding a Rickettsia felis outer membrane protein", cells comprising this DNA or methods of making proteins using this DNA.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Reiger et al (Glossary of Genetics and Cytogenetics, Classical and Molecular, 4th Ed., Springer-Verlay, Berlin, 1976) clearly define alleles as one of two or more alternative forms of a gene occupying the same locus on a particular chromosome..... and differing from other alleles of that locus at one or more mutational sites (page 17). Thus, the structure of naturally occurring allelic sequences are not defined. With the exception of SEQ ID NO:1, the skilled artisan cannot envision the detailed structure of the encompassed polynucleotides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Lts., 18 USPQ2d 1016.

Furthermore, In The Reagents of the University of California v. Eli Lilly (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Support for allelic variants is provided in the specification on page 8, lines 14-18 where it is disclosed that "Allelic or other variations of the sequences of SEQ ID NO:1, whether such nucleotide changes result in changes in the peptide sequence or not..... are also included" and on page 12, lines 26-31 where it is disclosed that allelic variants of DNA sequences which code for human SDF-5 protein coded for by the sequences of SEQ ID NO:1 also encode the novel factors described herein. However, no disclosure, beyond the mere mention of allelic variants is made in the specification. This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Therefore only 'an isolated nucleic acid molecule comprising SEQ ID NO:1' and 'an isolated nucleic acid molecule which encodes the amino acid as shown in SEQ ID NO:2', but not

the full breadth of the claims meets the written description provisions of 35 USC 112, first paragraph.

Allowable Subject Matter

7. Claims 4 and 5 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. Since 'an isolated nucleic acid molecule comprising SEQ ID NO:1' and 'an isolated nucleic acid molecule which encodes the amino acid as shown in SEQ ID NO:2' are allowable, expression vectors and host cells comprising this nucleic acid, as well as recombinant methods of producing proteins using this nucleic acid, would also be allowable.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is (703) 308-4242 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (703) 308-1742. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JENNIFER E. GRASER
PRIMARY EXAMINER
4/29/03